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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/064,749	08/13/2002	Robert David Darrow	RD27658	8455

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EXAMINER

LAMPRECHT, JOEL

ART UNIT	PAPER NUMBER
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3737

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/064,749

Applicant(s)

DARROW ET AL.

Examiner

Joel M. Lamprecht

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-17 and 19-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-17 and 19-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-10, 13-17, 19, 22-31, and 32 are rejected under 35 U.S.C.

102(b) as being anticipated by Dumoulin et al. (U.S. Patent No. 5,251,635).

1. Regarding Claims 1, 7, 13 and 23, Dumoulin et al. '635 teaches a medical device positioning system and method including a medical device adapted for internal use for performing the medical procedure, an imaging device (col. 1, lines 60-63), a medical device monitoring and positioning subsystem (col. 2, lines 2-10, 61-66, and 68) for monitoring the position of the medical device relative to a target region of interest within the subject and for providing feedback to an interface unit and responding to motion of at least one of the medical device or the subject in a predetermined fashion when the position of the medical device deviates from the target region of interest (col. 3, lines 1-4, 12-16 and 35-39), a tracking device, a processor coupled to the medical imaging device and the tracking device for generating images of the region of interest with a visual representation of the medical device superimposed on the images, where the processor is further adapted to monitor a position of the medical device relative to the region of interest and to respond to changes in the position and provide feedback to an interface and where the operator initiates image acquisition at a

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selected location through an interface which is adapted to respond to the operator's input (col. 4, lines 16-19 and col. 7, lines 24-43).

2. Regarding Claims 2, 4-6, 17, 19, 22, 24 and 25, Dumoulin et al. '635 teaches a monitoring subsystem that is adapted to receive configuration information that is tracking method information corresponding to the medical device (col. 3, lines 1-4 and 22-25), that has a predetermined response of activating the imaging system to acquire a new image in response to the movement of the medical device relative to the target region within the subject, that provides advisory feedback to the interface unit when the medical device deviates from a target position (col. 4, lines 19-21, 25-35, 42-46 and 68), where the advisory feedback is a visual icon representing the position of the device (col. 5, line 1 and col. 7, lines 24-39).

3. Regarding Claims 8-10, 14-16 and 26-31, Dumoulin et al. '635 teaches an imaging device that may be an MRI scanner, an X-ray device, a PET system, an ultrasound scanner or any other similar medical diagnostic imaging device; an invasive device that may be at least one of a biopsy needle guide, an invasive probe, an ablation device, a laparoscope and a therapeutic laser (col. 1, lines 60-63, col. 2, lines 25-28), an interface where the operator selects the desired position of the device and a coupling between the interface and the processor for displaying the images representing the region of interest and the medical device (col. 3, lines 1-4, col. 4, lines 22-48) where the interface is used for positioning the medical device and responding to movement of the medical device in real time, such that the feedback provided to the interface can be used to navigate

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the device to a region of interest (col. 7, lines 31-43 and 61-68 and col. 8, lines 1-3).

Claim Rejections - 35 USC § 103

4. Claim 32 is rejected under 35 U.S.C. 102(b) as anticipated by Dumoulin et al. or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dumoulin et al.

Regarding Claim 32, Dumoulin et al. disclose all that is listed above, and also discloses advisory feedback when the medical device deviates from a target position in the form of updating the image on the monitor or interface visual output of the system. While this embodiment does not explicitly disclose providing a text advisory, the monitor is capable of displaying text. In the alternative, it would have been obvious to one skilled in the art to modify the advisory from image feedback as taught by Dumoulin et al. to text feedback as an alternative functional equivalent to produce feedback to the operator in lieu of constantly updated images provides feedback to the user in a predetermined fashion that allows for the user to choose to terminate therapy, continue with therapy, move the device without moving the patient, or any other response that someone skilled in the art would reasonably provide.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 2, 11, 12, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoulin et al. '635 in view of Panescu et al. (U.S. Patent No. 5,916,163).

7. Dumoulin et al. '635 teaches all of the features of the present invention, but fails to teach that the monitoring and positioning subsystem receives configuration information about the device that is a model representation, where that information corresponds to a visual representation of the device for superimposing on the images acquired, and where the visual representation is a wire-frame model of the device.

8. In the same field of endeavor, Panescu et al. teaches a system for locating and positioning a catheter within a body where configuration information about the device is entered into the processing system (col. 6, lines 56-59). Panescu et al. also teaches that a graphical representation of the device may be provided and that the representation may be used in combination with the fluoroscopic images of the position of the device (col. 6, lines 31-46). Further, Panescu et al. teaches that a wire-frame image of the device may be used (col. 6, lines 47-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the configuration input scheme and visual representations of Panescu et al. with the system of Dumoulin et al. '635 in order to provide the operator with improved orientation of the device within the subject (see for motivation Panescu et al. at col. 5, lines 65-67 and col. 6, lines 6-12).

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9. Claims 6, 17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoulin et al. '635 in view of Twiss et al. (U.S. Patent No. 5,375,596).

10. Dumoulin et al. '635 teaches all of the features of the present invention except for expressly providing that the advisory feedback may be an audible advisory.

11. In the same field of endeavor, Twiss et al. teaches a method and apparatus for locating catheters or other devices within biological tissue where an audible tone is used to indicate proximity to the desired location (col. 7, lines 1-4 and 23-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the audible advisory of Twiss et al. in the system of Dumoulin et al. '635 so that the operator receives location information without the necessity of his looking away from the patient to a display screen.

12. Claims 1, 2, 4-10, 13-17, 19 and 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoulin et al. (U.S. Patent No. 5,211,165) in view of Dumoulin et al. '635.

13. Regarding Claims 1, 7, 10, 13, 23, 26 and 31, Dumoulin et al. '165 teaches a medical device positioning system and a method for positioning a device comprising an internal medical device, an imaging device, a medical device monitoring and positioning subsystem that monitors the position of the device and provides feedback to an interface, a tracking device, and a processor

coupled to the medical imaging device and tracking device for generating images (col. 2, lines 46-51, 53-57 and 61-65, col. 3, lines 23-27, col. 4, lines 4-7 and col. 7, lines 18-32). Dumoulin et al. '165 does not explicitly teach that the target region of interest is selected by an operator from an image, that the interface responds to operator input of coordinates of the desired target position of the medical device or that the subsystem has a predetermined response to movement of the subject or of the medical device relative to the target region. In the same field of endeavor, Dumoulin et al. '635 teaches that the operator initiates image acquisition at a selected location through an interface that is adapted to respond to the operator's input (col. 7, lines 38-43) and that the subsystem has a predetermined response to movement of the medical device relative to the target region (col. 7, lines 24-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine these features of the '635 patent with those of the '165 patent in order to provide imaging or therapy at the appropriate location and in order to provide improved placement of the device.

Regarding Claims 2, 4-6, 17, 19, 22, 24 and 25, Dumoulin et al. '165 teaches a monitoring subsystem that is adapted to receive configuration information that is tracking method information corresponding to the medical device, that has a predetermined response of activating the imaging system to acquire a new image in response to the movement of the medical device relative to the target region within the subject and that provides advisory feedback where the feedback is a visual icon representing the location of the device (col. 2, lines

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54-57, col. 3, lines 9-12, col. 4, lines 8-10, 14-24, 31-36 and 58-60 and col. 7, lines 26-32).

14. Regarding Claims 8, 9, 14, 15 and 27, Dumoulin et al. '165 teaches that the imaging device may be an MRI scanner, an X-ray device, a PET system or an ultrasound scanner and that the invasive device may be a guide wire, laparoscope, catheter, biopsy needle or other invasive devices (col. 1, lines 25-26 and 50, col. 7, lines 33-38).

15. Regarding Claims 16 and 28-30, Dumoulin et al. '165 teaches all of the features of the present invention except for expressly stating that there is a coupling between the interface and the processor that allows display of images and response to movement in real time and that the feedback may be used to navigate the device. In the same field of endeavor, Dumoulin et al. '635 teaches a coupling between the interface and the processor for displaying the images representing the region of interest and the medical device (col. 3, lines 1-4), where the interface is used for positioning the medical device and responding to movement of the medical device in real time, such that the feedback provided to the interface can be used to navigate the device to a region of interest (col. 2, lines 25-28 and col. 7, lines 31-39 and 61-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the real-time response of Dumoulin et al. '635 in the system of Dumoulin et al. & '165 in order to provide improved placement of the device. When inserting an invasive device into the body, both the ultimate location as well as the path the device takes to reach that location are critical in order to avoid unnecessary damage to

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tissues, therefore it would be obvious to use a system that provides a more accurate and contemporaneous location for the device.

16. Claims 2, 11, 12, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoulin et al. '165 in view of Dumoulin et al. '635 as applied to Claims 1, 13 and 23 above, and further in view of Panescu et al. Dumoulin et al. '165 in view of Dumoulin et al. '635 teaches all of the features of the present invention except that the monitoring subsystem receives configuration information about the device that is a model representation, where that information corresponds to a visual representation of the device for superimposing on the images acquired, and where the visual representation is a wire-frame model of the device.

17. In the same field of endeavor, Panescu et al. teaches a system for locating and positioning a catheter within a body where configuration information about the device is entered into the processing system (col. 6, lines 56-59). Panescu et al. also teaches that a graphical representation of the device may be provided and that the representation may be used in combination with the fluoroscopic images of the position of the device (col. 6, lines 31-46). Further, Panescu et al. teaches that a wire-frame image of the device may be used (col. 6, lines 47-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the configuration input scheme and visual representations of Panescu et al. with the system of Dumoulin et al. (165 in order to provide the operator with improved orientation of the device within the

subject (see for motivation Panescu et al. at col. 5, lines 65-67 and col. 6, lines 6-12).

Response to Arguments

18. Applicants' arguments filed 11/9/2006 have been fully considered but they are moot based on the grounds of new rejection.

19. Regarding Applicants' Petition to withdraw finality, the Examiner finds Attorney's Arguments persuasive and a rejection for that claim is provided herein.

20. Regarding Applicants' arguments with respect to the 35 U.S.C. § 102(b) rejection of Claims 1-19, 13-17, 19 and 22-30 over Dumoulin et al. (U.S. Patent No. 5,251,635). Applicants' argument does not overcome the rejection as Dumoulin et al. '635, discloses a device for repositioning a medical device within the target region of interest without moving the subject. The imaging device disclosed in Dumoulin et al. '635 is capable of both translational and rotational motion to facilitate any modifications in the area to be imaged, so it is understood that the subject of the procedure would not be required to move during tracking and imaging. The Examiner would like to direct Applicants' attention to Figure 1, of the current specification, which clearly shows the support arm for the imaging device moving, and that the support arm is not connected to the support table at all. The support table (labeled 110) and subject (labeled 112) are not moved, rather the *support arm*, and *imaging apparatus* seem to *move* to enable better viewing of the area of interest (column 7 lines 24-37). Specifically, in lines 27-30 where "The calculated position of the invasive device from tracking computer is supplied to a positioning means which controls the position and orientation of

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support arm in relation to support table" would imply that the moving parts (support arm) move in relation to the table, not the other way around.

Furthermore, the Examiner adds that in the Claims of Dumoulin et al. '635, specifically Claims 3-5, Dumoulin discloses at least a device that is well-known in the art to be capable of being moved relative to a patient without necessitating the movement of the patient (The case of a guide-wire). As is inherent with a device attached to a guide-wire or simply a guide-wire itself; the surgeon places and adjusts the position of the wire or device relative to the patient without moving the patient, based on the feedback from the imaging/locating device.

21. With respect to the argument that Dumoulin et al. '635 fails to teach a predetermined or pre-programmed response such as terminating therapy, acquiring a new image of the area of interest, or repositioning the medical device within the target region of interest without moving the subject or activating an audio or a text advisory feedback, the Examiner notes as above that the medical device (the imaging system) disclosed by Dumoulin et al. in '635 moves without moving the subject and also discloses automatic positioning of the field-of-view over the invasive device, which is a predetermined response, and additionally is preprogrammed to acquire additional images of the area of interest during the procedure. Examiner's advanced argument, that feedback provided via a visual icon can be used to navigate the device to a region of interest, is still valid as the device moves to the target area without moving the subject as noted above.

Conclusion

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22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joel M. Lamprecht whose telephone number is (571) 272-3250. The examiner can normally be reached on Monday-Friday 7:30AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JML

8/24/06



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